

REMARKS

Applicant respectfully requests favorable reconsideration of this application in light of the following remarks. By the present amendment, Applicant has amended claims 12 and 26, cancelled claims 21-22, and added claims 35-39. Claim 26 was amended to correct a typographical error. Claims 12-20 and 23-39 are thus pending in this application. No new matter has been added.

35 U.S.C. § 102(b) Rejections

As an initial matter, claim 34 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,374,264 to Wadsworth (hereinafter "Wadsworth") and by U.S. Patent No. 5,895,383 to Niedospial (hereinafter "Niedospial"). In the Office Action, claims 12-19, 24-29, and 34 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Niedospial. Applicant respectfully traverses this rejection.

Applicant has amended independent claim 12 to recite a fluid transfer device, including, among other things, a piercing mandrel including a piercing portion that is "substantially conically shaped and widening toward the lid portion" and a sealing portion "having a substantially tapered shape, a smallest cross-section of the sealing portion adjoining the piercing portion of the piercing mandrel, the sealing portion having a smallest diameter greater than a largest diameter of the piercing portion."

The Office Action states that "[t]he piercing mandrel [of Niedospial] further includes a sealing portion (section 113 and surrounding areas) formed integrally with the lid portion (see the cross section of Figure 6) that contacts the piercing portion . . . the sealing portion being configured to contact the elastic stopper (@ section 69) when the bead is substantially disposed in the space." Office Action at 2-3. The Office Action

further contends that the sealing portion of the piercing mandrel is “substantially conically shaped,” such that it widens toward the top of the mandrel. *Id.* at 3.

Applicant respectfully asserts that to the contrary, section 113 of Niedospial and surrounding areas (characterized by the Examiner as a sealing portion) is not substantially conically shaped, nor does it have a substantially tapered shape, as is required by claim 12. Therefore, this claim element is not found within the four corners of Niedospial.

The specification of Niedospial explicitly teaches “[a]n external ring 69 projecting towards the center of the stopper designed to engage an annular groove 113 of the spike.” Niedospial, col. 6, ll. 2-4. This description and the cross sections clearly shown in Figs. 6 and 8 of Niedospial confirm that section 113 does not have a “substantially tapered shaped,” as required by claim 12.

Further, the very existence of this annular groove 113 (again, what the Examiner has characterized as the sealing portion of Niedospial) shown in Figs. 6 and 8 necessitates that the sealing portion of the piercing mandrel does not have a smallest diameter greater than a largest diameter of the piercing portion, an additional requirement of claim 12.

Accordingly, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. § 102(b).

Claims 13-19 and 24-29 depend from claim 12 and are therefore allowable over Niedospial for at least the same reasons explained above.

In addition, new dependent claim 35 recites that the sealing portion of claim 12 is “further configured to seal a tear in the elastic stopper formed upon eccentric application

of the fluid transfer device to the elastic stopper.” The configuration of Niedospial precludes the sealing portion, as characterized by the Examiner, from sealing a tear in the elastic stopper formed as a result of eccentric application and, as such, does not include this claimed feature. Applicant therefore respectfully requests timely allowance of claim 35.

Independent claim 34 recites a fluid transfer device, including, among other things, a sealing portion “extending from the lid section along part of the piercing portion and ending in a substantially abrupt step, the substantially abrupt step being configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space”

The Office Action is silent with respect to this required element of claim 34. Specifically, the Office Action does not address whether Niedospial discloses “a sealing portion ending in a substantially abrupt step, the substantially abrupt step configured to engage and seal the pierced portion of the elastic stopper.” Niedospial does not disclose such features. Niedospial discloses a cylindrical shaft 112 including an annular groove 113 configured to engage an external ring 69 of stopper 60. Niedospial, col. 5, l. 64 - col. 6, l. 5, ll. 32-34. Niedospial does not show any engaging or sealing *of the pierced portion* of the elastic stopper by element 113 (again characterized by the Examiner as a sealing portion). Element 69 of Niedospial is an *external ring* (having an open center through which point 116 of shaft 112 passes) and thus is not a pierced portion of stopper 60. As disclosed, the sharp tip 116 of shaft 112 of spike 110 penetrates the recessed target area 68 of stopper 60. Col. 6, l. 67 - col. 7, l. 1. For at least these reasons, Niedospial does not anticipate claim 34.

As noted, claim 34 also stands rejected under 35 U.S.C. § 102(b) as being anticipated by Wadsworth. Claim 34 requires a sealing portion “ending in a substantially abrupt step, the substantially abrupt step being configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space such that the sealing portion partially enters the elastic stopper.” Wadsworth does not disclose or suggest such features. Wadsworth discloses a fitting 10 for positioning over a liquid entry portion of a culture bottle. Affixed to the center of the body portion 14 of fitting 10 is a needle 26. Through needle 26 extends a lumen 22 in fluid communication with a Luer lock structure 16 at one end and terminating in a sharp point 23 at the other. Wadsworth, col. 2, l. 54 - col. 3, l. 2. Wadsworth explicitly discloses “[a]n elastomeric sheath valve 24 preferably is attached to the bottom surface of body portion 14 and surrounds needle 26, including its point 23.” Wadsworth, col. 3, ll. 3-5. In Wadsworth, needle 23 pierces sheath 24 before penetrating through the septum 45. Sheath 24 is intended to seal needle 23 when no fluid transfer is occurring. Wadsworth does not disclose or suggest that sheath 24 seals the pierced element. Wadsworth, col. 3, ll. 2-11; col. 4, ll. 22-27. Further, Applicant submits that Wadsworth does not disclose a sealing portion partially entering the elastic stopper because the disclosed sealing portion 24 of Wadsworth (which, again, does not seal the pierced element) may contact the top surface of the stopper but travels no farther into the stopper. Wadsworth, Fig. 4. Therefore, Wadsworth does not anticipate claim 34.

Accordingly, for at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34 under 35 U.S.C. § 102(b).

35 U.S.C. § 103(a) Rejections

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 5,358,501 to Meyer (hereinafter "Meyer"). Claim 20 depends from claim 12 and is therefore allowable over Niedospial in view of Meyer for at least the same reasons explained above. Moreover, Meyer does not remedy the noted deficiencies of Niedospial. Accordingly, for this additional reason, the rejection of claim 20 is not sustainable and should be withdrawn.

Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 3,977,555 to Larson (hereinafter "Larson"). Claim 23 depends from claim 12 and is therefore allowable over Niedospial for at least the same reasons explained above. Moreover, Larson does not remedy the noted deficiencies of Niedospial. Accordingly, for this additional reason, the rejection of claim 23 is not sustainable and should be withdrawn.

Claims 30-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Niedospial in view of U.S. Patent No. 6,558,365 to Zinger et al. (hereinafter "Zinger"). Claims 30-33 depend from claim 12 and are therefore allowable over Niedospial for at least the same reasons explained above. Further, Zinger does not remedy the noted deficiencies of Niedospial. Accordingly, for this additional reason, the rejection of claims 30-33 is not sustainable and should be withdrawn.

Claim 34 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Published Application No. 2002/0121496 to Thiebault et al. (hereinafter "Thiebault") in view of Niedospial. Applicant respectfully traverses this rejection and the Examiner's comment that claim 34 "is nearly identical to claim 12." Office Action at 10.

Applicant disagrees with this characterization of claim 34 and notes that while claims 12 and 34 may have some features in common, each includes additional features that render it separately patentable.

Independent claim 34 recites a fluid transfer device, including, among other things, a sealing portion ending in a substantially abrupt step “configured to engage and seal the pierced portion of the elastic stopper when the bead is received in the space”

The Office Action is silent with respect to this required element of claim 34. In fact, Applicant points out that this particular rejection appears to consider claim limitations found in claim 12, as opposed to claim 34. Office Action at 7-9.

Nonetheless, according to Thiebault:

Because the transfer set 20 is adapted to transfer fluid between the vial 22 and a second container (not shown) through the inner tubular portion 52, the inner and outer tubular portions 52 and 50, respectively, are preferably sealingly supported on the stopper 30. . . . the proximal portion 52a of the inner tubular portion 52 includes an annular sharp edge 56 . . . sealing the communication between the vial 22 and the inner tubular transfer member 52. The proximal portion 50a of the outer tubular portion 50 also includes an annular rib 58 preferably having a sharp circular edge which provides a redundant seal and prevents entry of foreign matter into the tubular transfer member 20.

Para. [0024], Fig. 1. The piercing member 42 of Thiebault includes “a reduced diameter piercing portion 82 having a relatively sharp piercing end 84.” Para. [0026], Fig. 1.

Thus, Thiebault does not disclose a sealing portion configured to engage and seal the *pierced portion* of the elastic stopper, as required in claim 34. This deficiency of Thiebault is not remedied by the disclosure of Niedospial, as previously discussed.

Accordingly, for at least this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 34 under 35 U.S.C. § 103(a).

New Claims

Applicant adds new independent claim 36 and dependent claims 35 and 37-39 to vary the scope of protection recited in the claims. Claims 35-39 find non-limiting support at least in Figs. 3-5, 8, and 9 and on pg. 3, ll. 1-8, 14-15; pg. 4, ll. 18-25; and pg. 9, l. 19 - pg. 10, l. 2 of the originally-filed application. Applicant submits that the prior art does not disclose all the features of claims 35-39. To the extent the prior art rejections of independent claims 12 and 34 are relevant to new independent claim 36, Applicant provides the following comments:

Claim 36 recites, among other things, a “piercing mandrel the piercing mandrel being substantially continuously conically shaped along its length, widening from a piercing tip to the lid portion, . . . wherein the piercing mandrel is configured to substantially concurrently seal the pierced portion of the elastic stopper as the bead is received in the space.” Though Applicant certainly does not purport to present herewith a complete evaluation of the prior art with respect to claim 36, Applicant submits that at the very least neither Wadsworth, Thiebault, Zinger, Larson, or Meyer includes a piercing mandrel that is “substantially continuously conically shaped along its length” and that “widen[s] from a piercing tip to the lid portion.” Applicant also submits that at the very least neither Wadsworth, Niedospial, Thiebault, Zinger, or Meyer includes a piercing mandrel configured to substantially concurrently seal the pierced portion of the elastic stopper as the bead is received in the space.

Conclusion

In view of the foregoing reasons, Applicant respectfully requests reconsideration of this application, withdrawal of all of the outstanding rejections, and timely allowance of all pending claims.

The Office Action contains statements and characterizations regarding the claims and the related art. Applicant declines to subscribe automatically to any statement or characterization in the Office Action, regardless of whether it is addressed above.

Please grant any extensions of time required to enter this amendment and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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